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DEC 2 0 2013

510(k) Summary

Submitted by:	Advanced Medical Solutions (Plymouth) Ltd. Western Wood Way Langage Science Park Plymouth, Devon. PL7 5BG United Kingdom Tel: +44 (0)1752 209955 Fax: +44 (0) 1752 209956
Contact Person:	Kay M^{c}Grath Senior Regulatory Affairs Associate Advanced Medical Solutions Ltd
Date of Summary:	12 September 2013
Device Trade Name:	Barle Tissue Adhesive 2
Common or Usual Name:	Topical Skin Adhesive
Classification Name:	Tissue Adhesive (21 CFR 878.4010)
Product Code:	MPN
Predicate Device(s):	Barle Tissue Adhesive (K123133) LiquiBand® (K122446)
Device Description:	Barle Tissue Adhesive 2 is a sterile, topical tissue adhesive containing 2-octyl cyanoacrylate for wound closure. It is applied to easily approximated skin edges and polymerizes within minutes. Barle Tissue Adhesive 2 is supplied in a single patient use configuration.
Indication for Use:	Barle Tissue Adhesive 2 topical skin adhesive is intended for topical applications only, to hold closed easily approximated skin edges of wounds from surgical incisions, including punctures from minimally invasive surgery and simple, thoroughly cleansed, trauma induced lacerations. Barle Tissue Adhesive 2 topical skin adhesive may be used in conjunction with, but not in place of, deep dermal stitches.

Technological Characteristics	The technological characteristics of Barle Tissue Adhesive 2 are substantially equivalent to the predicate devices. The main reasons for the submission of Barle Tissue Adhesive 2, following clearance of the Barle Tissue Adhesive (K123133), is because of these changes: • Modification of the applicator body design to remove actuation "wings". • Addition of a microbial barrier claim.
Substantial Equivalence:	Barle Tissue Adhesive 2 is substantially equivalent to Barle Tissue Adhesive (K123133) and LiquiBand® Flow Control Topical Skin Adhesive (K122446) with regard to Indication For Use, target population, intended application, mechanism of action and performance at achieving its intended use; in addition Barle Tissue Adhesive 2 is substantially equivalent to LiquiBand® Flow Control with regard to the microbial barrier claim.
Conclusion	Extensive design verification, functional and performance testing have been conducted. Barle Tissue Adhesive 2 was evaluated in tests to establish a performance and safety profile in accordance with the Class II Special Controls Guidance Document: Tissue Adhesive for Topical Approximation of Skin, May 30 2008. Based on the non-clinical testing carried out, Barle Tissue Adhesive 2 is considered as safe, as effective and performs as well as the legally marketed predicate devices – Barle Tissue Adhesive (K123133) and LiquiBand® Flow Control (K122446).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Advanced Medical Solutions (Plymouth) Limited
Ms. Kay McGrath
Senior Regulatory Affairs Associate
Western Wood Way
Langage Science Park
Plympton, Devon United Kingdom PL7 5BG

December 20, 2013

Re: K132243
Trade/Device Name: Barle Tissue Adhesive 2
Regulation Number: 21 CFR 878.4010
Regulation Name: Tissue adhesive
Regulatory Class: Class II
Product Code: MPN
Dated: December 5, 2013
Received: December 9, 2013

Dear Ms. McGrath:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joshua C. Nipper -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: K132243

Device Name: Barle Tissue Adhesive 2

Model Number: 000-869

Indications For Use: Barle Tissue Adhesive 2 topical skin adhesive is intended for topical applications only, to hold closed easily approximated skin edges of wounds from surgical incisions, including punctures from minimally invasive surgery and simple, thoroughly cleansed, trauma induced lacerations. Barle Tissue Adhesive 2 topical skin adhesive may be used in conjunction with, but not in place of, deep dermal stitches.

Prescription Use: **YES** (Part 21 CFR 801 Subpart D) AND/OR Over-the-Counter Use: **NO** (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jiyoung Dang -S